for databases released through the HCUP Central Distributor depending on the type of database. The fee for sale of state-level data is determined by each participating Statewide Data Organization and reimbursed to those organizations.

Information collected in the HCUP Application process will be used for two purposes only:

1. Business Transaction: In order to deliver the HCUP databases and software, contact information is necessary for shipping some types of HCUP data on disk (or any other media used in the future).

2. Enforcement of the HCUP DUA: The HCUP DUA contains several restrictions on use of the data. Most of these restrictions have been put in place to safeguard the privacy of individuals and establishments represented in the data. For example, data users can only use the data for research, analysis, and aggregate statistical reporting and are prohibited from attempting to identify any persons in the data. Contact information on HCUP DUAs is retained in the event that a violation of the DUA takes place.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden associated with the applicants' time to order any of the HCUP databases. An estimated 1,500 persons will order HCUP data annually. Each of these persons will complete an application (10 minutes), the DUA training (15 minutes) and a DUA (5 minutes). The total burden is estimated to be 750 hours annually.

Exhibit 2 shows the estimated annualized cost burden associated with the applicants' time to order HCUP data. The total cost burden is estimated to be $29,662 annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
HCUP Application Form	1,500	1	10/60	250
HCUP DUA Training	1,500	1	15/60	375
HCUP DUA	1,500	1	5/60	125
Total	4,500	na	na	750

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
HCUP Application Form	1,500	250	$39.55	$9,887
HCUP DUA Training	1,500	375	39.55	14,831
HCUP DUA	1,500	125	39.55	4,944
Total	4,500	750	na	29,662

* Based upon the mean of the average wages for Life Scientists, All Other (19–1099), National Compensation Survey: Occupational Employment Statistics, May 2017 National Occupational Employment and Wage Estimates United States, U.S. Department of Labor, Bureau of Labor Statistics. *http://www.bls.gov/oes/current/oes_nat.htm#b29-0000*.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection.

All comments will become a matter of public record.

Francis D. Chesley, Jr.,

Acting Deputy Director.

[FR Doc. 2018–27359 Filed 12–17–18; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Diagnostic and Treatment of Clinical Alzheimer's-Type Dementia (CATD)

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review of *Diagnostic and Treatment of Clinical Alzheimer's-type Dementia (CATD),* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before January 17, 2019.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301–427–1496 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Diagnostic and Treatment of Clinical Alzheimer's-type Dementia (CATD).* AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *Diagnostic and Treatment of Clinical Alzheimer's-type Dementia (CATD),* including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: *https://effectivehealthcare.ahrq.gov/topics/alzheimers-type-dementia/protocol.*

This is to notify the public that the EPC Program would find the following information on *Diagnostic and Treatment of Clinical Alzheimer's-type Dementia (CATD)* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* please provide a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

The Key Questions

KQ 1: In adults with CATD, what are the efficacy and harms of prescription pharmacological interventions versus placebo/inactive control for treatment of cognition, function, and quality of life?

KQ 1a: In adults with CATD, does the efficacy of prescription pharmacological interventions versus placebo/inactive control vary as a function of patient characteristics (*i.e.,* age, sex, race/ethnicity, depression, pre-treatment cognitive or functional level/CATD stage, living setting)?

KQ 2: In adults with CATD, what are the efficacy and harms of nonprescription pharmacological interventions versus placebo/inactive control for treatment of cognition, function, and quality of life?

KQ 2a: In adults with CATD, does the efficacy of nonprescription pharmacological interventions versus placebo/inactive control vary as a function of patient characteristics (*i.e.,* age, sex, race/ethnicity, depression, pre-treatment cognitive or functional level/CATD stage, living setting)?

KQ 3: In adults with CATD, what are the comparative effectiveness and harms of prescription pharmacological interventions versus other active interventions for treatment of cognition, function, and quality of life?

KQ 3a: In adults with CATD, what are the comparative effectiveness and harms of prescription pharmacological interventions versus other prescription pharmacological interventions for treatment of cognition, function, and quality of life?

KQ 3b: In adults with CATD, what are the comparative effectiveness and harms of prescription pharmacological interventions versus nonprescription pharmacological interventions for treatment of cognition, function, and quality of life?

KQ 3c: In adults with CATD, what are the comparative effectiveness and harms of prescription pharmacological interventions versus nonpharmacological interventions for treatment of cognition, function, and quality of life?

KQ 3d: In adults with CATD, does the comparative effectiveness of prescription pharmacological interventions versus other active interventions for treatment of cognition, function, and quality of life vary as a function of patient characteristics (*i.e.,* age, sex, race/ethnicity, depression, pre-treatment cognitive or functional level/CATD stage, living setting)?

KQ 4: In adults with CATD and behavioral and psychological symptoms of dementia (BPSD), what are the efficacy and harms of prescription pharmacological interventions versus placebo/inactive control for treatment of BPSD?

KQ 4a: In adults with CATD and BPSD, what are the efficacy and harms of prescription pharmacological interventions versus placebo/inactive control for reducing frequency and severity of future BPSD?

KQ 4b: In adults with CATD and BPSD, does the efficacy of prescription pharmacological interventions versus placebo/inactive control for reducing frequency and severity of future BPSD vary as a function of patient characteristics (*i.e.,* age, sex, race/ethnicity, depression, pre-treatment cognitive or functional level/CATD stage, pre-treatment BPSD severity, living setting)?

KQ 4c: In adults with CATD and BPSD, what are the efficacy and harms of prescription pharmacological interventions versus placebo/inactive control for acute treatment of BPSD?

KQ 4d: In adults with CATD and BPSD, does the efficacy of prescription pharmacological interventions versus placebo/inactive control for acute treatment of BPSD vary as a function of patient characteristics (*i.e.,* age, sex, race/ethnicity, depression, pre-treatment cognitive or functional level/CATD stage, pre-treatment BPSD severity, living setting)?

KQ 5: In adults with CATD and BPSD, what are the efficacy and harms of nonprescription pharmacological interventions versus placebo/inactive control for treatment of BPSD in adults with CATD and BPSD?

KQ 5a: In adults with CATD and BPSD, what are the efficacy and harms of nonprescription pharmacological interventions versus placebo/inactive control for reducing frequency and severity of future BPSD?

KQ 5b: In adults with CATD and BPSD, does the efficacy of nonprescription pharmacological interventions versus placebo/inactive control for reducing frequency and severity of future BPSD vary as a function of patient characteristics (*i.e.,* age, sex, race/ethnicity, depression, pre-treatment cognitive or functional level/CATD stage, pre-treatment BPSD severity, living setting)?

KQ 5c: In adults with CATD and BPSD, what are the efficacy and harms of

nonprescription pharmacological interventions versus placebo/inactive control for acute treatment of BPSD?

KQ 5d: In adults with CATD and BPSD, does the efficacy of nonprescription pharmacological interventions versus placebo/inactive control for acute treatment of BPSD vary as a function of patient characteristics (*i.e.,* age, sex, race/ethnicity, depression, pre-treatment cognitive or functional level/CATD stage, pre-treatment BPSD severity, living setting)?

KQ 6: In adults with CATD and BPSD, what are the comparative effectiveness and harms of prescription pharmacological interventions versus other active interventions for treatment of BPSD?

KQ 6a: In adults with CATD and BPSD, what are the comparative effectiveness and harms of prescription pharmacological interventions versus other prescription pharmacological interventions for reducing frequency and severity of future BPSD?

KQ 6b: In adults with CATD and BPSD, what are the comparative effectiveness and harms of prescription pharmacological interventions versus nonprescription pharmacological interventions for reducing frequency and severity of future BPSD?

KQ 6c: In adults with CATD and BPSD, what are the comparative effectiveness and harms of prescription pharmacological interventions versus nonpharmacological interventions for reducing frequency and severity of future BPSD?

KQ 6d: In adults with CATD and BPSD, does the comparative effectiveness of prescription pharmacological interventions versus other active interventions for reducing frequency and severity of future BPSD vary as a function of patient characteristics (*i.e.,* age, sex, race/ethnicity, depression, pre-treatment cognitive or functional level/CATD stage, pre-treatment BPSD severity, living setting)?

KQ 6e: In adults with CATD and BPSD, what are the comparative effectiveness and harms of prescription pharmacological interventions versus other prescription pharmacological interventions for acute treatment of BPSD?

KQ 6f: In adults with CATD and BPSD, what are the comparative effectiveness and harms of prescription pharmacological interventions versus nonprescription pharmacological interventions for acute treatment of BPSD?

KQ 6g: In adults with CATD and BPSD, what are the comparative effectiveness and harms of prescription pharmacological interventions versus nonpharmacological interventions for acute treatment of BPSD?

KQ 6h: In adults with CATD and BPSD, does the comparative effectiveness of prescription pharmacological interventions versus other active interventions for acute treatment of BPSD vary as a function of patient characteristics (*i.e.,* age, sex, race/ethnicity, depression, pre-treatment cognitive or functional level/CATD stage, pre-treatment BPSD severity, living setting)?

KQ 7: In adults with suspected CATD, what are the accuracy, comparative accuracy, and harms of different individual cognitive diagnostic tests and their combinations for making the diagnosis of CATD as defined by full clinical evaluation and/or neuropsychological testing with explicit diagnostic criteria?

KQ 7a: Do the accuracy and comparative accuracy of cognitive tests for making the diagnosis of CATD as defined by full clinical evaluation and/or neuropsychological testing with explicit diagnostic criteria vary as a function of patient characteristics (*i.e.,* age, sex, race/ethnicity, education, pre-testing cognitive or functional level CATD stage)?

KQ 8: In adults with a clinical diagnosis of CATD, what are the accuracy, comparative accuracy, and harms of brain imaging, CSF, and blood tests for diagnosing pathologically confirmed Alzheimer's disease as the underlying etiology?

KQ 8a: Do the accuracy and comparative accuracy of brain imaging, CSF, and blood tests for pathologically confirmed Alzheimer's disease as the underlying etiology of CATD vary as a function of patient characteristics (*i.e.,* age, sex, race/ethnicity, depression, education, pre-testing cognitive or functional level CATD stage)?

TABLE 1—PICOTS
[Populations, interventions, comparators, outcomes, timing, settings/study design]

KQ	Population	Intervention	Treatment comparator or diagnostic reference standard	Health outcomes & harms	Timing	Setting	Study design
KQ 1–3: Drug treatment efficacy, comparative effectiveness & harms on cognition, function & quality of life.	Adults with CATD ≥50 years of age *Patient characteristics to be assessed as possible treatment effect modifiers:* Age, Sex, Race/ethnicity, Depression, Pre-treatment cognitive or functional level/CATD stage, Living setting.	*Prescription pharmacologic (drug) treatment:* Cholinesterase inhibitors, NMDA antagonists. *Nonprescription pharmacologic (drug) treatment:* OTC supplements, Vitamins, Herbals.	*For efficacy comparisons:* Placebo, Other inactive control. *For comparative effectiveness comparisons:* Prescription drug treatment, Nonprescription drug treatment, Nondrug treatment.	*Efficacy and comparative effectiveness:* Change in patient cognition (global screen, multidomain, memory, executive function, language, attention), function, or QOL on validated test. Change in disease stage based on validated test. Change in patient "at home" IADL or ADL function. Change in patient residence to different level of independence. *Harms:* *General:* FDA defined SAEs, Withdrawals due to AEs. *Psychiatric:* Somnolence, Confusion/Delirium. *Nonpsychiatric:* Falls, Extrapyramidal symptoms, Stroke. Mortality (all-cause, CVD, non-CVD).	≥24 weeks	*Cognitive outcomes:* Community-dwelling, Assisted living. *Functional & QOL outcomes:* Community-dwelling, Assisted living, Nursing home.	*Efficacy and comparative effectiveness:* RCT, CCT, systematic review of RCTs or CCTs. *Harms:* RCT, CCT, controlled prospective cohort studies with ≥1,000 participants, systematic review of any of these study designs.
KQ 4–6: Drug treatment efficacy, comparative effectiveness & harms on BPSD.	Adults with CATD ≥50 years of age with BPSD (studies specified BPSD inclusion criterion). *Patient characteristics to be assessed as possible treatment effect modifiers:* Age, Sex, Race/ethnicity, Pre-treatment cognitive or functional level/CATD stage, Pre-treatment BPSD severity, Living setting.	*Prescription pharmacologic treatment:* Cholinesterase inhibitors, NMDA antagonists, Antipsychotics, second generation (any) and first generation (only haloperidol), Antidepressants, Anti-seizure/mood stabilizers, Anxiolytics, benzodiazepine, Anxiolytics, other Hormonal agents (Disinhibited sexual behavior only), Cannabinoids, Combinations. *Nonprescription pharmacologic treatment:* OTC supplements, Vitamins, Herbals.	*Efficacy comparisons:* Placebo, Other inactive control. *Comparative effectiveness comparisons:* Prescription drug treatment, Nonprescription drug treatment, Nondrug treatment.	*Efficacy and comparative effectiveness:* *Primary:* Change in the frequency and/or severity of patient BPSD* on validated tests, Agitation/aggression, Psychosis, Depression, Anxiety, Disinhibited sexual behavior, Change in patient QoL on validated test, Change in validated general behavior scale. *Secondary:* Change in caregiver/staff outcomes on validated tests, Depression, Global stress/distress, QOL, Burden. *Harms:* *General:* FDA defined composite SAE outcome, Withdrawals due to AE. *Psychiatric:* Somnolence, Confusion/Delirium. *Nonpsychiatric:* Falls, Extrapyramidal symptoms, Stroke, Mortality (all-cause, CVD, non-CVD).	*Agitation, aggression, psychosis or Disinhibited sexual behavior outcomes:* ≥2 weeks. *Depression or anxiety outcomes:* ≥24 weeks.	Community-dwelling, Assisted living, Nursing home.	*Efficacy and comparative effectiveness:* RCT, CCT, systematic review of RCTs or CCTs. *Harms:* RCT, CCT, controlled prospective cohort studies ≥1,000 participants, systematic review of any of these study designs.

KQ 7–8: Diagnostic test accuracy & harms (also see Table 2 below).	*Cognitive tests:* Adults ≥50 years of age with suspected CATD. *Biomarker tests only:* Adults ≥50 years of age with clinical syndrome of CATD. *Patient characteristics to be assessed as possible effect modifiers of diagnostic test accuracy:* Age, Sex, Race/ethnicity, Education, Depression. Pre-test cognitive or functional level/CATD stage.	*Brief, validated cognitive tests:* Global (brief screens, multi-domain batteries), Single domain tests (memory, executive, language, attention. *Biomarker tests:* *Brain imaging:* CT/MRI: Medial temporal atrophy/hippocampal volume, Cortical thickness, DTI indices PET: ^{18}F-FDG PET, Amyloid PET, ^{11}C-PiB and fluorinated tracers (e.g. florbetapir, flutemetamol, florbetaben), Tau PET fMRI: Resting state and task specific activation SPECT: Resting state cerebral perfusion *CSF tests:* Aβ42, Aβ42/Aβ40 ratio, t-tau, p-tau, t-tau/Aβ42 ratio, p-tau/Aβ42 ratio, neurofilament light protein *Blood tests:* Aβ42, Aβ42/Aβ40 ratio, APP *Combinations*	*Cognitive tests:* Full clinical evaluation and/or neuropsychological testing with explicit diagnostic criteria. *Biomarker tests:* Post-mortem neuropathological confirmation of AD.	*Accuracy and comparative accuracy (e.g., TP, FP, TN, FN, sensitivity, specificity, PPV, NPV).* Of cognitive tests for confirming clinical syndrome of CATD. Of biomarker tests for confirming that etiology of CATD is AD. *Harms:* *Psychological or behavioral* True positive: Labeling stigma False positive: Incorrect diagnosis, Labeling stigma, Side effects of unneeded interventions (e.g., restrictions on independence). False negative: Unexplained symptoms, Failure to make appropriate interventions (e.g., safety precautions, future planning). Any test result: Patient or caregiver mental distress. *Physical:* Directly from diagnostic tests: Pain, Infection, Headache, Radiation.	Any	Community-dwelling, Assisted living.	*Accuracy and comparative accuracy:* Controlled observational studies (*i.e.,* cross-sectional, retrospective cohort, case control); systematic review of controlled observational studies. *Harms:* Controlled observational studies (i.e., cross-sectional, retrospective cohort, case control, prospective cohort); systematic review of controlled observational studies.

* For this report, two psychological symptoms that are components of BPSD have been excluded due to their coverage in recent, high quality systematic reviews—apathy and sleep disturbances.[18 19] In addition, wandering was also eliminated, as this symptom is usually treated with nonpharmacologic interventions, which are not covered as interventions in this review.

† Strength of evidence (SOE) will be evaluated for the 1–2 most commonly reported validated treatment efficacy outcomes for each of the following test categories: disease stage, global cognitive screening tests, global multidomain cognitive tests, memory, executive functioning, language, attention, function, quality of life, BPSD agitation/aggression, and the harms outcome of serious adverse events. Additional treatment outcomes will be considered for SOE grading when available data allow. For diagnostic tests, SOE will be graded for the 1–2 most commonly reported validated tests for each of the following categories: global cognitive screening tests, global multidomain cognitive tests, memory, MRI, PET, and CSF tests. Additional diagnostic testing outcomes will be considered for SOE grading when available data allow.

Aß = beta amyloid, AD = Alzheimer's dementia, ADL = activities of daily living, AE = adverse events, APOE = apolipoprotein E, APP = amyloid precursor protein, BPSD = behavioral and psychological symptoms of dementia, CATD = clinical Alzheimer's-type dementia, CCT = controlled clinical trial, CSF = cerebrospinal fluid, CT = computed tomography, CVD = cardiovascular disease, DTI = diffusion tensor imaging, FDG = fluorodeoxyglucose, fMRI = functional magnetic resonance imaging, FN = false negative, FP = false positive, IADL = instrumental activities of daily living, MCI = mild cognitive impairment, MRI = magnetic resonance imaging, NMDA = N-methyl-D-aspartate, NPV = negative predictive value, OTC = over-the-counter, PET = positron emission tomography, PPV = positive predictive value, p-tau = abnormally phosphorylated tau, QOL = quality of life, RCT = randomized clinical trial, ROC = receiver operating characteristic, SAE = serious adverse events, SPECT = single-photon emission computed tomography, TN = true negative, TP = true positive, t-tau = total tau.

TABLE 2—PRESCRIPTION DRUGS USED FOR TREATMENT OF CATD COGNITION, FUNCTION, QUALITY OF LIFE OR BPSD

Class of drug	Drug name(s)
Cholinesterase inhibitor	Donepezil*, rivastigmine*, galantamine*.
NMDA receptor antagonist	Memantine*.
Cholinesterase inhibitor/NMDA receptor antagonist combination	Donepezil/Memantine*.
1st generation (typical) antipsychotic	only Haloperidol.
2nd generation (atypical) antipsychotic	*e.g.,* Risperidone, quetiapine, olanzapine, aripiprazole, clozapine.
Anti-depressant, selective serotonin-reuptake inhibitor (SSRI)	*e.g.,* Citalopram, escitalopram, sertraline, fluoxetine, fluvoxamine, paroxetine.
Anti-depressant, serotonin-norepinephrine reuptake inhibitor (SNRI)	*e.g.,* Duloxetine, venlafaxine.
Anti-depressant, other†	*e.g.,* Trazodone, bupropion, mirtazapine.
Anti-seizure/mood stabilizer	*e.g.,* Valproate, gabapentin, carbamazepine, lamotrigine.
Anti-anxiety, benzodiazepine	*e.g.,* Clonazepam, diazepam, lorazepam, temazepam, alprazolam.
Anti-anxiety, other	Buspirone.
Mixed	Dextromethorpan/Quinidine.
Hormones (antiandrogens, estrogens, gonadotropin-releasing hormone analogues).	*e.g.,* medroxyprogesterone acetate, cyproterone acetate, leuprolide.
Cannabinoids	*e.g.,* medical marijuana.

*US FDA approved indication for Alzheimer's dementia.
†Excludes MAO-inhibitor, tricyclic and tetracyclic antidepressants.
BPSD = behavioral and psychological symptoms of dementia, CATD = clinical Alzheimer's-type dementia, NMDA = N-methyl-D-aspartate, SSRI = selective serotonin reuptake inhibitor, SNRI = selective norepinephrine reuptake inhibitor.

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Acting Deputy Director.

[FR Doc. 2018–27361 Filed 12–17–18; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10465]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by February 19, 2019.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10465 Minimum Essential Coverage

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Minimum Essential Coverage; *Use:* The final rule titled ''Patient Protection and Affordable Care Act; Exchange Functions: Eligibility for Exemptions; Miscellaneous Minimum Essential Coverage Provisions,'' published July 1, 2013 (78 FR 39494) designates certain types of health coverage as minimum essential coverage. Other types of coverage, not statutorily designated and not designated as minimum essential coverage in regulation, may be recognized by the Secretary of Health and Human Services (HHS) as minimum essential coverage if certain substantive and procedural requirements are met. To be recognized as minimum essential coverage, the coverage must offer substantially the same consumer protections as those enumerated in the Title I of Affordable Care Act relating to non-grandfathered, individual health insurance coverage to ensure consumers are receiving adequate coverage. The final rule requires sponsors of other coverage that seek to have such coverage recognized as minimum essential coverage to adhere to certain procedures. Sponsoring organizations must submit to HHS certain information about their coverage and an attestation that the plan substantially complies with the provisions of Title I of the Affordable Care Act applicable to non-grandfathered individual health insurance coverage. Sponsors must also provide notice to enrollees informing